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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/769,536

01/30/2004

Zaijie Wang

UIC0002US

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05/08/2006

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EXAMINER

HARLE, JENNIFER I

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/769,536

Applicant(s)

WANG, ZAIJIE

Examiner

Jennifer I. Harle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 28 and 29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 28 and 29 are pending. Claims 1-27 were cancelled by Applicants' Amendment dated April 28, 2006 .

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claim 28, drawn to a method for preventing or reversing the chronic actions of an opium alkaloid comprising administering a calcium calmodulin dependent protein kinase (CaMKII), classified in various classes and subclasses depending upon whether it is a protein 514, a nucleic acid 536 or a small chemical compound.
 - II. Claim 29, drawn to a composition comprising an inhibitor of the activity of calcium calmodulin dependent protein kinase II, an opium alkaloid and an excipient, classified in various classes and subclass depending upon whether it is a protein, peptide or small chemical compound.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process, i.e. it can be used for the treatment of pain. See the Specification at pp. 1 and 21. Moreover, the method for preventing or reversing chronic actions of an opium alkaloid, i.e. addiction, tolerance or withdraw can be practiced with the materially different product by

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administering partial agonists of the NMDA receptor (See US Patent 5,523,323 or FDA

Approves Two Drugs to Treat Opiate Dependence, Forbes, October 8, 2002, pg.1,

<http://www.webprowire.com/summaries/266443.html>, printed March 21, 2005).

Searching the inventions of Groups I and II together would impose a serious search burden. In the instant case, the search for the composition and the method are not coextensive. Group II encompasses a vast plethora of molecules that range from chemicals to peptides to polypeptides for CaMKII inhibitors and then the plethora of opium alkaloids; The search for Group I would require different text searching for the various methods encompassed in preventing or reversing chronic actions of an opium alkaloid, i.e. tolerance, addiction and withdraw to name a few. Prior art which teaches CaMKII inhibitor(s) and/or opiate alkaloid(s) would not necessarily be applicable to the method. Moreover, even if the (CaMKII inhibitor(s) and/or opiate alkaloid were known, the method which uses the products may be novel or unobvious in view of the preamble or active steps.

Because these inventions are distinct for the reasons given above and the search required for each group is not required for the other group because each group requires a different non-patent literature search and thus imposes a serious search burden, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species: 1) for claims 28 and 29 - inhibitors of calcium calmodulin dependent kinase II and 2) claim 29 - opiate alkaloids. The species are independent or distinct because the specific calcium calmodulin dependent protein kinase inhibitors are not disclosed as capable of use together, are structurally very different (see Specification pp. 21-24 – include proteins, chemical inhibitors,

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small peptides, all of which differ structurally within their own groupings) and more over, they can be used for different methods, such as treatment and prevention of arrhythmias and as inhibitors for other calcium calmodulin dependent protein kinases. US Patent 6,518,245, Col. 7, lines 47-55. The opium alkaloids can be used for more than just treating pain, for example, morphine has a plethora of uses, i.e. check diarrhea, suppress cough, ease dyspnea and facilitate anesthesia as set forth in the specification pp. pg. 5, codeine can be used as a cough suppressant and hypnotic, diacetylmorphine (heroin) can be used as a hypnotic and papaverine is structurally different and would have a different classification. These examples can be found in the Specification on pages 21-24 and in the previous claims.

4. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 28 and 29 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Claim 29 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant

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timely traversed the restriction (election) requirement in the reply filed on April 28, 2006.

However, Applicant failed to comply with the Election of Species requirement and is still required to elect a CaMKII inhibitor.

6. Applicant's election with traverse of Claim 28, i.e. now Group I in the reply filed on April 28, 2006 is acknowledged. The traversal is on the ground(s) that there would be no additional search burden because a search of the method would be expected to reveal the composition. This is not found persuasive because the composition contains additional ingredients not found in the method, which would need to be searched and as set forth above a search for the method would not necessarily encompass a search for the composition or vice versa. Also as stated above it would be burdensome because of the divergent search strategies and keyword searching involved in the method versus just the composition. Additionally Applicant argues that the election of species is improper because they have clarified the nature of the inhibitor and the nature of the inhibitor and the inhibitor would no longer be required to be a nucleic acid. However, CaMKII inhibitors can be used for a different purposes and while they may share a common characteristic of inhibiting the activity of CaMKII this is not enough to make them distinct, however, the different inhibitors have different classifications depending upon whether they are small peptides, proteins or chemical compounds and would require a different field of search, i.e. structure or sequence searching, they do not overlap just because they have the same title their divergent structures would make them mutually exclusive and not obvious variants and as previously set forth they can have a different mode of operation or effect. As to the opiate alkaloid, Applicant's admit that there is continuous research into making new analgesics, which would include opiate alkaloids. However, opium alkaloids can be used for different purposes

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and while some may share a common core papaverine does not and thus this is not enough to make them distinct, as they will have different classifications, would require different fields of search, i.e. structure, text, they do not overlap just because they have the same title and their at least one divergent structure would make them mutually exclusive and not obvious variants and as previously set forth they can have a different mode of operation or effect.

The requirement is still deemed proper and is therefore made FINAL.

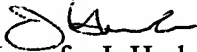
7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jennifer I. Harle
Examiner
Art Unit 1654

May 3, 2006